

## **REMARKS**

Claims 1-57 are pending and were restricted. Claims 33-57 were elected. Non-elected claims 1-32 are canceled without prejudice.

### **Double Patenting**

Claims 33-57 are provisionally rejected under obviousness-type double patenting over claims 21-24, 26-29, and 52-56 of copending application No. 10/440,804. Applicant will submit a Terminal Disclaimer upon receipt of allowable claims.

### **Claim Rejections Under 35 U.S.C. §112**

Claims 33-57 are rejected under 35 U.S.C. §112, ¶2, as indefinite. With respect to claim 44, Applicant respectfully asserts that one skilled in the art would find definite the term "derivative", applied to barbituric acid, thiobarbituric acid, and ascorbic acid, and the term "substituted" applied to thiourea. By way of example only, for substituted thiourea the substitutions could be alkyl and/or aryl group(s). By way of example only, barbituric acid derivatives denote substituted thiobarbituric acid, and substitutions could be alkyl and/or aryl group(s). By way of example only, ascorbic acid derivatives could be a salt such as a sodium salt. With respect to the other claims, Applicant has amended them to overcome this rejection, and respectfully requests its withdrawal.

### **Claim Rejections Under 35 U.S.C. §103**

Claims 33-39, 41-44, and 46-57 are rejected under 35 U.S.C. §103(a) as obvious over Falsafi. Claims 33-39, 41-44, and 46-57 are rejected under 35 U.S.C. §103(a) as obvious over Falsafi in view of Engelbrecht or Zimmerman. Applicant respectfully disagrees.

Both Applicant and Falsafi identify the shortcomings of current self-adhesive two-part compositions, namely, that the catalyst part comprising both the acidic compounds and the oxidizing agent (e.g. benzoyl peroxide (BPO)) of the redox initiator system, have poor stability (Applicant's specification page 2, line 19 to page 3, line 9; Falsafi at column 2, line 62 to column 3, line 1 and comparative examples A and B).

Falsafi discloses a method for improving the stability of the catalyst part of the two-part composition by making a heterogeneous catalyst system. In Falsafi, either the redox initiator/oxidizing agent (e.g. BPO) or the polyacid is insoluble or has very limited solubility in the catalyst solution, so that one or both of them exist in a disperse phase. This slows the chemical degradation of the peroxide oxidizing agent and prolongs the shelf-life of the catalyst composition.

For example, Falsafi column 1, line 12: "...At least one of the polyacid and redox catalyst exist in a disperse phase". Falsafi column 2, lines 4-7: "...One uniqueness of the present invention is that at least one of the following components exist in a disperse phase: the polyacid, the oxidizing agent, and the reducing agent." Falsafi column 2, lines 15-18: "...The inventors have discovered that such long-term stability can be achieved when at least one of the following components is in the disperse phase: the polyacid and the redox catalyst".

Falsafi defines his "disperse phase" as follows: (column 2, lines 19-23):

The term 'disperse phase' means generally a two phase system where one phase contains discrete particles distributed throughout a bulk substance, the particle being the disperse phase, and the bulk substance being the continuous phase.

Falsafi (column 8, lines 40-60), also discloses kits containing instructions such as dual barrel syringes and their use:

Part A resides in the first barrel and part B resides in the second barrel. Part A is a dispersion that comprises, e.g., at least one polyacid, at least one polymerizable component, and an oxidizing agent, where the polyacids and/or the oxidizing agent is dispersed in the polymerizable component. Part B comprises water, reactive fillers, and at least one reducing agent where the reducing agent can be dispersed in polymerizable component"

See also Falsafi claims 1 and 2:

1. ... (a) a part A comprising discrete, solid particles of a polymer comprising acid functional dispersed in a polymerizable component; ...
2. The dental composition of claim 1 wherein part A further comprises discrete particles of the oxidizing agent dispersed in the polymerizable component...

(In an alternative method to improve stability of the catalyst part of the two-part composition, Falsafi discloses use of a particular monoacid that dissolved in the polymerizable component (Falsafi column 2, lines 53-61). The only example (Example 1) in Falsafi using this method and this particular monoacid and having adhesion data showed zero (0 MPa) adhesion. A material having no adhesion is not an adhesive.)

Thus, Falsafi's method to enhance the stability of a known two-part adhesive composition is to introduce inhomogeneity, i.e., a dispersed phase, to the system (or to employ a specific monoacid).

Falsafi does not teach, disclose, or suggest a method to improve stability or adhesion of the composition by varying the ratio of catalyst part to the base part, as Applicant claims. Falsafi discloses only a 1:1 ratio of catalyst part to base part. For example, Falsafi column 12, lines 32-34: "... Each example was prepared by transferring 0.2 gm of part A and 0.2 gm of part B to a dental mixing pad and mixing the components by hand with a spatula". This is a 1:1 ratio.

In contrast, Applicant's claims require a ratio of Part A (catalyst part) to Part B (base part) above 1:1, to increase the acidity of the mixed composition. This results in enhanced adhesion or enhanced stability to the composition, subsequently analyzed.

As Applicant has disclosed:

The present invention ... results in an enhanced bond strength as the total concentration of acidic compound(s) in the mixed composition is increased, or as the ratio of a first paste, containing the acidic compound(s) or a higher concentration of acidic compound(s), relative to a second paste, containing no acidic compound(s) or a lower concentration of acidic compound(s), is increased over 1:1 (by volume) (page 6, lines 16-22).

A first paste contains all the acidic component(s) or a higher concentration of acidic component(s) relative to the second paste. The ratio of the first paste and the second paste in the mixed composition is greater than 1:1 by volume), and provides enhanced bond strengths to a dental substrate (for example, dentine, enamel, dental metal alloy, porcelain) (page 3, lines 16-20).

In the inventive method, an increase in the ratio yields an increase in the bond strength (page 10, lines 15-16).

Applicant's claimed method enhances the bond strength by increasing the total concentration of acidic compound(s) in the mixed composition by increasing the ratio of a first paste (catalyst paste, see example on page 25 lines 1-23) containing the acidic compound(s) or a higher concentration of acidic compound(s), relative to a second paste, containing no acidic compound(s) or a lower concentration of acidic compound(s), to over 1:1 (by volume).

Applicant discovered that increasing the ratio effectively increases the total concentration of acidic compound(s) in the mixed composition without raising the concentration of acidic compound(s) in the catalyst part of the two-part composition. The traditional way of enhancing the adhesive property of a two-part adhesive composition was to increase the acidic compound(s) concentration in the catalyst part, so that the overall concentration of acidic compound(s) in the mixed composition can be increased when the catalyst and the base were mixed at 1:1 ratio. However, there is an upper limit to which the concentration of acidic compound(s) in the catalyst part can be increased. Any concentration increase of acidic compound(s) in the catalyst part would increase the degradation rate of the initiator (oxidizing agent) and the monomers, and therefore would negatively affect the shelf-life of the catalyst. That is the shortcoming or limitations of 1:1 mixing ratio. For that reason, Falsafi's total concentrations of acid compound(s) is no more than 50% and preferably about 5-25% of the total composition (Falsafi column 3, lines 48-50), using his 1:1 ratio.

For example using Falsafi's method, if the total concentration of acidic compound(s) in Part A is at the upper limit of 50% and with a 1:1 mixing ratio, the maximum total concentration of acidic compound(s) in the mixed composition would be just 25% ( $50\% \times 1/2$ ). In contrast, using Applicant's method with a mixing ratio of 10:1, the maximum total concentration of acidic compound(s) in the mixed composition would be 45.5% ( $50\% \times 10/11$ ), much higher than the 25% achievable using Falsafi's 1:1 mixing ratio. This increased concentration of acid compound(s) and resulting improvement in adhesive property is achieved without increasing the concentration of acid compound(s) in catalyst part, therefore not negatively affecting the stability of the catalyst part.

For a given two-part adhesive composition with a given acidic compound(s) concentration in the catalyst part, the adhesive property of the mixed composition can be improved by employing Applicant's method without negatively impacting the stability of the catalyst part, i.e. by increasing the ratio of the catalyst part (containing the acidic compound(s) or a higher concentration of acidic compound(s) relative to the base part) to the base part. Or, to maintain the same adhesive property or overall acidic compound(s) concentration in the mixed composition, the stability of the catalyst part can be significantly

enhanced by employing the increased mixing ratio since the acidic compound(s) concentration the catalyst past can now be significantly reduced.

Applicant's method for employing a ratio of a first paste (catalyst paste), containing the acidic compound(s) or a higher concentration of acidic compound(s), relative to a second paste (base paste), containing no acidic compound(s) or a lower concentration of acidic compound(s), over 1:1 (claim 33), or 1.05:1 to 20:1 (claim 50), or preferably 2:1 to 10:1 (claim 51) would effectively enhance the adhesive property. This improvement in adhesive strength is shown in Applicant's Example 2. A bond strength of 8.87 MPa to dentin substrate was achieved with a 4:1 (by volume) ratio, doubling that achieved with 1:1 ratio (4.48 MPa in Applicant's Example 1). This enhancement in adhesion is achieved without negatively impact the stability of the catalyst paste, because the catalyst composition is kept the same and only the ratio of catalyst paste to base paste to produce the mixed composition during application is increased.

With respect to claim 56, Applicant respectfully disagrees with the Examiner's interpretation of the reference. The Examiner incorrectly stated that "DTS of 17 MPa and CS of 69.6 MPa taught in Table 2 would meet the instant bond strength of claim 56". Diametral Tensile Strength (DTS) and Compressive Strength (CS) are the bulk mechanical properties for Falsafi's dental composition itself, and have nothing to do with adhesive strength (or bond strength). Adhesive Strength is the adhesion of an adhesive material to another material (or substrate). Falsafi's adhesion data are listed in Table 2, below the DTS and CS data for the compositions of Falsafi's Examples 1 and 2. In fact, DTS and CS have little relationship to adhesion or adhesive strength. Falsafi's Example 1 composition had DTS of 17.9 MPa and CS of 69.6 MPa, but it had no adhesion (0 MPa). Falsafi's Example 2 composition had much lower DTS (13.8 MPa) and CS (41.4 MPa) than that of Example 1, but had better adhesion (4.8 MPa). Falsafi's examples used a 1:1 ratio (column 12, lines 32-34: "... Each example was prepared by transferring 0.2 gm of part A and 0.2 gm of part B to a dental mixing pad and mixing the components by hand with a spatula".

Thus, Applicant respectfully asserts that Falsafi does not render obvious claims 33-39, 41-44, and 46-57, either alone or in view of Engelbrecht or Zimmerman because neither Engelbrecht nor Zimmerman, combined with Falsafi, teach, suggest, or motivate Applicant's claimed method.

In summary, Applicant's claimed method results in a self-adhesive composition by increasing the mixing ratio of the catalyst part (containing acidic compound(s) or a higher concentration of acidic compound(s) relative to base part) to the base part. Falsafi does not teach, suggest, or motivate this method, and thus does not render obvious Applicant's claims, each of which require this ratio.

## **CONCLUSION**

Based on the foregoing, Applicant believes this application is now in complete condition for allowance and respectfully requests that a Notice of Allowance be issued.

No fees are believed due, but the Examiner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 23-3000. The Examiner is invited to contact the undersigned representative with any questions.

Respectfully submitted,  
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